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10/583,012	06/15/2006	Veronique Hall-Goulle	TM/4-22999/A/PCT	6112

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EXAMINER

BLAND, LAYLA D

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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03/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,012	Applicant(s) HALL-GOULLE ET AL.	
	Examiner LAYLA BLAND	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 11-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/11/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

This application is a national stage entry of International Application No. PCT/EP04/53332, filed December 8, 2004, which claims priority to European Application No. 03104773.1, filed on December 18, 2003. The copy of certified copy of the priority has been filed with the instant Application.

Applicant's election with traverse of Group XII and the species 116a shown on page 38 of the specification in the reply filed on January 22, 2008 is acknowledged. The traversal is on the ground(s) that Reuscher et al., US 5,728,823, which was cited to show that Groups I-XXXVI are not linked by the same special technical feature, does not anticipate the claims. This is not found persuasive because, although Example 10 was cited erroneously and does not anticipate the claims, other teachings within Reuscher et al. do. The genus taught by Reuscher [columns 1-4 and claims 1-16] includes compounds which meet the limitations of the instant claims, as will be discussed in this office action.

The requirement is still deemed proper and is therefore made FINAL.

It is noted that Applicant did not identify the claims encompassing the elected invention. Claim 9 (which does not encompass a derivative having a reactive group of the heterocyclic series) and claims 11-15 are withdrawn from consideration as being drawn to a non-elected invention. Claims 1-8, 10, and 16 are examined on the merits herein.

Claim Objections

Claim 10 is objected to because of the following informalities: the number 1 was not removed from the claim when the claim was amended. Thus the claim reads “n is 1 or 21.” It is assumed that the claim should read “n is 1 or 2.” Appropriate correction or clarification is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8, 10, and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds wherein Z_1 or Z_2 are triazine, pyrimidine, quinoxaline, does not reasonably provide enablement for compounds wherein Z_1 or Z_2 are any heterocyclic moiety further comprising any substitutions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in *Wands* states, “Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not

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be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention.

"Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to compounds of formula (1a) or (1b), wherein A is N and Z_1 or Z_2 is a radical of the heterocyclic series. The specification (page 9) states that suitable reactive radicals from the heterocyclic series contain 4, 5, or 6-membered rings and are substituted by a removable atom or group. No guidance is provided as to which groups are considered removable. Thus, the claims taken together with the specification imply that compounds meeting the above definition wherein Z_1 or Z_2 is any heterocyclic group, having any substitution, are claimed.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Reactive cyclodextrin derivatives comprising triazine, pyrimidine, and quinoxaline rings are known in the art, as taught by Reuscher et al. (US 5,728,823, March 17, 1988, PTO-1449 submitted September 11, 2006) [claims 1-16] and Kulke et al. (WO 03/093325, November 13, 2003) [pages 6-7].

However, the skilled artisan would not consider any and every other heterocyclic group as equivalent to these, and the synthesis and use of such is expected to be non-trivial. As stated in the preface to a recent treatise:

“Most non-chemists would probably be horrified if they were to learn how many attempted syntheses fail, and how inefficient research chemists are. The ratio of successful to unsuccessful chemical experiments in a normal research laboratory is far below unity, and synthetic research chemists, in the same way as most scientists, spend most of their time working out what went wrong, and why. Despite the many pitfalls lurking in organic synthesis, most organic chemistry textbooks and research articles do give the impression that organic reactions just proceed smoothly and that the total synthesis of complex natural products, for instance, is maybe a labor-intensive but otherwise undemanding task. In fact, most syntheses of structurally complex natural products are the result of several years of hard work by a team of chemists, with almost every step requiring careful optimization. The final synthesis usually looks quite different from that originally planned, because of unexpected difficulties encountered in the initially chosen synthetic sequence. Only the seasoned practitioner who has experienced for himself the many failures and frustrations which the development (sometimes even the repetition) of a synthesis usually implies will be able to appraise such work.....Chemists tend not to publish negative results, because these are, as opposed to positive results, never definite (and far too copious).....” Dorwald F. A. *Side Reactions in Organic Synthesis*, 2005, Wiley: VCH, Weinheim pg. IX of Preface.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance and working examples for reactive cyclodextrin derivatives comprising a triazine ring.

However, the specification does not provide guidance or working examples for derivatives comprising other heterocyclic moieties.

"Specific operative embodiments or examples of the invention must be set forth. Examples and description should be of sufficient scope as to justify the scope of the claims. Markush claims must be provided with support in the disclosure for each member of the Markush group. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula." See MPEP 608.01(p).

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to the breadth of the claims and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

MPEP §2164.01 (a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

It is noted that claim 7 was not included in this rejection because the only reactive heterocyclic ring included in this claim is a triazine derivative.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 10, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (and dependent claims) recites the limitations "substituted or unsubstituted," alkyl or aryl groups. Neither the claim nor the specification defines what these substituents can be. Note that exemplification of substituents does not amount to a definition. Without a definition of what the substituents can be, it is impossible to determine the metes and bounds of the claim.

Claim 1 (and dependent claims) recites the limitation "reactive radical...of the heterocyclic series." The specification (page 9) states that suitable reactive radicals from the heterocyclic series contain 4, 5, or 6-membered rings and are substituted by a removable atom or group, but no guidance is provided as to which groups are considered removable and no guidance is given regarding the number and identity of heteroatoms which can be present in members of the heterocyclic series. Thus, it is impossible to ascertain the metes and bounds of the claim. At this time, "removable group" is considered to be any moiety until further clarification is given.

Claims 1 and 2 recite definitions for variables which are not given in the alternative. See the definition for Q₂ and Q₃ in claim 1. See the definition for Q₁, Q₂, and Q₃ in claim 2. For example, Q₁ should not read as “hydrogen, benzyl, and C₁-C₄ alkyl”, but “hydrogen, benzyl, or C₁-C₄ alkyl.”

Claim 6 recites the limitation “non-reactive substituent.” Neither the claim nor the specification defines what these substituents can be. Note that exemplification of substituents does not amount to a definition. Without a definition of what the substituents can be, it is impossible to determine the metes and bounds of the claim.

Claim 7 contains a moiety (3c') which is ambiguous as to the substituent attached to nitrogen. The substituent attached to nitrogen is drawn as "H, Me, Et." Only one substituent may be attached to the same position in a structure drawing and commas should not be present in a chemical structure. The substituent(s) should be clearly defined.

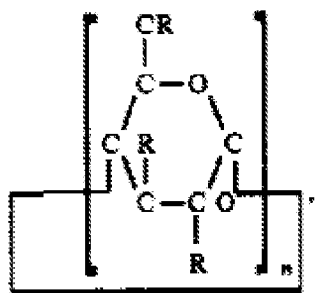
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

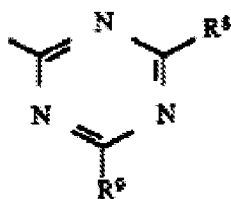
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 10, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reuscher et al. (US 5,728,823, March 17, 1998, PTO-1449 submitted September 11, 2006).

Reuscher et al. teach reactive cyclodextrin derivatives having nitrogen-containing heterocycles [see abstract]. The cyclodextrin derivatives are of formula I, shown below:



Wherein R is OH, OR¹, or R². In a preferred embodiment, R² is -R³_m-(CHR⁴)-R⁵-R⁶, where R³ and R⁵ can be NH or N-alkyl, and R⁶ is the heterocycle shown below:

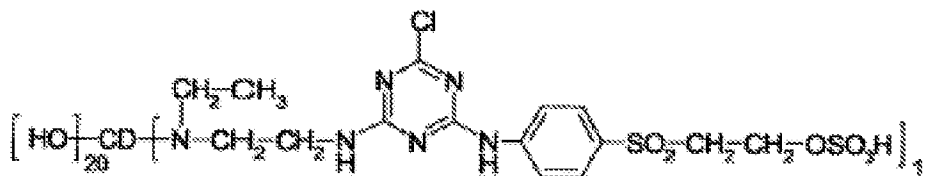


R⁸ and R⁹, shown on the above heterocycle, can be halogen, hydroxyl, alkoxy, NR² or N-phenyl, wherein the phenyl can be substituted with groups such as Cl, SO₂CH₂CH₂OSO₃H and CH₂SO₂CH₂CH₂OSO₃H. [columns 1-3]

The compounds are useful for finishing textiles [column 13, line 23 - column 15, line 26].

Reuscher et al. do not exemplify the species elected in the instant application, although the species does fall within the genus taught by Reuscher et al.

It would have been obvious to one of ordinary skill in the art to prepare the following compound, which is the elected species in this application:



Although Reuscher et al. do not exemplify this particular species, the species is taught as part of a genus of compounds which are useful for textile finishing, which is the same utility disclosed in the instant invention. Thus, the skilled artisan could have prepared this species and could have predicted that it would have utility in the textile industry.

It is noted that, although the elected species is not encompassed by all the rejected claims, the rejection over Reuscher et al. was deemed to be appropriate to those claims as well because the instantly claimed genus has substantial overlap and common utility with the genus of Reuscher et al. The major difference seen between the two genera is that the instant genus requires that the reaction group be linked to the cyclodextrin via a nitrogen, while the genus of Reuscher et al. teaches O, S, N, or OC=O in that position. This is a small number of identified, predictable variables and one of ordinary skill in the art could have prepared compounds with these variables and reasonably expected to achieve products which would be useful in the textile industry. Thus, the claims are obvious over Reuscher et al.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623